



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

9898 01 JUL -2 P1 58

JUN 11 2001

Mitchell A. Goldstein, Esq.  
Babener & Associates  
Bank of America Financial Center  
121 S.W. Morrison  
Suite 1020  
Portland, Oregon 97204-3140

Dear Mr. Goldstein:

This is in response to your letter to the Food and Drug Administration (FDA) dated May 30, 2001 on behalf of Tianshi Health Products, Inc., Everett, Washington. In your letter, you asked us to explain the basis for our position, stated in a letter to your client dated March 30, 2001, that the statement "maintain a healthy blood sugar level" is not a claim that may be made for dietary supplements pursuant to 21 U.S.C. 343(r)(6).

In our March 30, 2001 letter, we stated that the claim "...maintain a healthy blood sugar level" would not be an appropriate structure/function claim under 21 U.S.C. 343(r)(6). In the preamble to the January 6, 2000 final rule (see 65 FR 1000), FDA stated that health maintenance claims that do not imply disease treatment or prevention would be acceptable structure function claims. We stated that if the health maintenance claim did not use terms that are so closely identified with a specific disease or that so clearly referred to a particular at-risk population, we believed that such a claim could be a structure/function claim under 21 U.S.C. 343(r)(6) (see discussion at 65 FR 1018).

You stated in your letter that you believe that the claim "...maintain a healthy blood sugar level" is an appropriate structure/function claim that does not imply disease treatment, prevention, or mitigation because we stated in the preamble to the final rule that a claim such as "use as part of your diet to help maintain a healthy blood sugar level" would be an acceptable structure/function claim. We disagree. We believe that any claim that a product is intended to maintain normal (or healthy) blood glucose levels is an implied disease claim. This conclusion is based on the fact that a claim about external intervention to affect blood glucose levels is implicitly a claim to correct a defect in blood glucose levels because it is not necessary to improve, modify, or otherwise affect blood glucose unless it is impaired.

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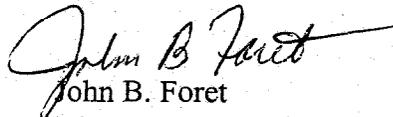
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Page 2 - Mr. Mitchell A. Goldstein

However, a claim that a product is important or plays a role in the maintenance or regulation of blood glucose that is already normal or within normal limits could be an appropriate structure/function claim, depending on the context. As we discussed in the preamble to the final rule, the context in which a particular claim is made is important in determining whether a claim may be a disease claim or a structure/function claim. Consequently, if the context of a claim about a product intended to affect blood glucose clearly and unambiguously makes clear that the product is not intended to have an effect on abnormal blood glucose (for example, the claim in the preamble of the January 6, 2000 final rule which you cited in your letter), then such a claim may be an acceptable structure/function claim under 21 U.S.C. 343(r)(6). But, the claim that your client submitted to us does not contain such context. The claim only states that "the product" will bring about the achieved effect, it does not mention any context about its use in a dietary context, nor does it explicitly place the context of the claim as being on "blood glucose levels that are already within the normal range." Consequently, we are not persuaded that the position taken in our March 30, 2001 letter is incorrect and we believe that the subject claim is not an acceptable structure/function claim under 21 U.S.C. 343(r)(6).

Please contact us if we may be of further assistance.

Sincerely,



John B. Foret  
Director

Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling,  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Seattle District Office, Compliance Branch, HFR-PA340

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (file, r/f)

HFS-810 (Foret)

HFS-811 (Moore)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-607 (Bayne Lisby)

HFV-228 (Betz)

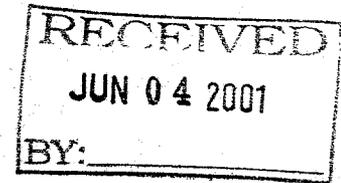
GCF-1 (Nickerson)

f/t:rjm:HFS-811:6/6/01:tianshi.adv:disc56

LAW OFFICES  
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May 30, 2001

Mr. John B. Foret  
Director, Division of  
Compliance and Enforcement  
Office of Nutritional Products,  
Labeling and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition  
Food and Drug Administration  
200 "C" Street S.W. (HFS-810)  
Washington, D.C. 20204

Re: Our File No. 15377-1

Attention: Robert J. Moore

Dear Mr. Foret:

This law firm represents Tianshi Health Products, Inc. We have been asked to respond to your correspondence of March 30, 2001 (copy enclosed) in which you state that the claim "...maintain a healthy blood sugar level..." does not meet the requirements of 21 U.S.C. 343 (r)(6).

It is our client's position that the above claim does not suggest an intended use to treat, prevent, cure or mitigate any type of disorder. Simply referring to "healthy blood sugar levels" does not imply an abnormality or disease state. Moreover, the specific objection raised in your letter (i.e., that the submitted claim suggests an intended use to treat, prevent, cure or mitigate "disorders of blood glucose levels") appears to be inconsistent with previous statements published by FDA in the Federal Register. In the preamble to the January 2000 final regulations governing structure/function claims, the agency states that the claim "use as part of your diet when

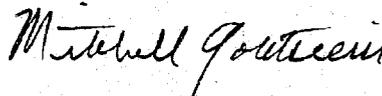
Letter to Mr. John B. Foret  
May 30, 2001

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taking insulin to help maintain a healthy blood sugar level" is not acceptable under section 101.93 (g)(2)(vii) of the regulations. However, the agency goes on to note that "if the statement were changed to 'use as part of your diet to help maintain a healthy blood sugar level,' the claim would be considered acceptable." 65 Fed. Reg. 1027. Since the claim submitted by our client is essentially identical to the "acceptable" structure/function claim published by the agency, we believe that our client's claim is likewise permissible under 21 U.S.C. 343(r)(6). Therefore, we respectfully request that you reconsider the objection raised in your correspondence of March 30, 2001.

Thank you for your assistance in this matter. We look forward to hearing from you at your earliest convenience.

Very truly yours,



Mitchell A. Goldstein

MAG/lrb

cc: Mr. Yan (via email)  
Maggie Li



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

MAR 30 2001

Ms. Maggie Li  
Vice President  
Tianshi Health Products, Inc.  
728-134th Street, SW  
Suite 222  
Everett, Washington 98204

Dear Ms. Li:

This is in response to your letter of March 16, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Tianshi Health Products, Inc. is making the following claim, among others, for the product Tianshi High Absorption Calcium Drink:

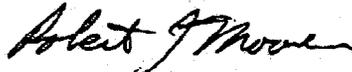
"...maintain a healthy blood sugar level..."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate disease, namely disorders of blood glucose levels. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

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Please contact us if we may be of further assistance.

Sincerely,

  
JBF

John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

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- FDA, Seattle District Office, Office of Compliance, HFR-PA340